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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/537,118 03/29/00 DUGGER H PHC03, 0-008

001815 HM12/0608  
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EXAMINER

HAGHTIGHATIAN, M

ART UNIT PAPER NUMBER

1619

*3*

DATE MAILED:

06/08/01

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No.	Applicant(s)
	09/537,118	DUGGER, HARRY
	Examiner	Art Unit
	Mina Haghigian	1619

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1)  Responsive to communication(s) filed on 25 January 2001 .

2a)  This action is **FINAL**.                    2b)  This action is non-final.

3)  Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

4)  Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5)  Claim(s) \_\_\_\_\_ is/are allowed.

6)  Claim(s) 1-25 is/are rejected.

7)  Claim(s) \_\_\_\_\_ is/are objected to.

8)  Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

9)  The specification is objected to by the Examiner.

10)  The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11)  The proposed drawing correction filed on \_\_\_\_\_ is: a)  approved b)  disapproved.

12)  The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a)  All b)  Some \* c)  None of:  
1.  Certified copies of the priority documents have been received.  
2.  Certified copies of the priority documents have been received in Application No. \_\_\_\_.  
3.  Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.

14)  Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

15)  Notice of References Cited (PTO-892) 18)  Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_  
16)  Notice of Draftsperson's Patent Drawing Review (PTO-948) 19)  Notice of Informal Patent Application (PTO-152)  
17)  Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_. 20)  Other: \_\_\_\_\_

## DETAILED ACTION

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 6-8, 11-12 and 18-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite due to being unduly alternative. Further, a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. In the present instance, claim 1 recites the broad recitation of concentration ranges for active component, polar and non-polar solvents and propellants, and the claim also recites other narrower or broader (in the case of propellant) range/limitation. Claim 1 is also vague and indefinite because it is not clear which of the solvents is suitable for each active component. Claim 1 also vague and indefinite due to “:2-10%”. This may be a typing error.

Claims 6-7 and 18-19 are vague and indefinite due to “the solvent”. These claims are dependent on claim 1, which recites two types of solvents. Claims 8, 11, 12 and 18 are vague and indefinite due to typing/spelling errors. These errors are: in claim 8 “odansetron”, claim 11 “odansitron”, in claim 12 “needed” and in claim 18 “a selected”.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-5, 7-9, 12-19 and 24-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dugger, III (5,955,098) in view of Klokkers-Bethke et al (5,370,862).

Dugger teaches buccal aerosol spray or capsule using a non-polar solvent, which provides biologically active compounds for rapid absorption through the oral mucosa, resulting in fast onset of effect. The buccal aerosol spray of formulations I and II are listed with the concentration ranges of the components in column 1 lines 34-67 in details. Dugger also teaches the propellants for spray to be N-pentane, N-butane, isobutane, iso-pentane, neo-pentane and mixtures thereof, meeting limitations of instant claim 16, (col. 3, lines 27-35).

Dugger teaches the preferred solvents as, fatty acids C<sub>2</sub> – C<sub>6</sub> esters including triglycerides, vegetable oils such as soya oils, corn oil and C<sub>7-18</sub> hydrocarbons of a linear or branched configuration, meeting limitations of instant claim 18, (col. 3, lines 40-49). Also disclosed are the preferred flavoring agents which are peppermint, oil of spearmint, citrus oil, fruit flavors and combinations thereof, thus meeting instant claim 9, (col. 3, lines 59-62).

Dugger also discloses that active substances include alkaloids, antihistamines, steroid hormones, non-steroidal anti-inflammatories, analgesics, anti-depressants and benzodiazepines such as temazepam (a sleep inducing agent), meeting limitations of instant claims 24 and 25, (col. 3, lines 63-67). Dugger lacks specific teachings on polar solvents and miglyol.

Klokkers-Bethke teaches pharmaceutical aerosol spray for treating an angina attack including a container having a liquid composition therein comprising 0.1 to 2 weight percent of nitroglycerin, 2 to 60 weight percent of ethanol, 2 to 60 weight percent of propylene glycol, 10 to 50 weight percent of propellants, (see paragraph bridging columns 3 and 4). Klokkers-Bethke also teaches miglyol as another suitable polar solvent for use in these types of compositions, thus meeting limitations of the instant claim 19, (see table 2).

It would have been obvious to a person of ordinary skill at the time the invention was made to have modified the teachings of Dugger of buccal non polar spray or capsule, by substituting the polar solvent as taught by Klokkers-Bethke, because

having the ability of producing aerosol compositions containing active components and either polar or non polar solvents provides a broader range of options and allows for production of a variety of therapeutic agents in an aerosol form.

Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dugger and Klokkers-Bethke as applied to claims 1-5, 7-9, 12-19 and 24-25 above, and further in view of Robinson et al (6,071,539).

The teachings of Dugger and Klokkers-Bethke were discussed above.

Robinson teaches effervescent granules having a controllable rate of effervescence. The composition contains binders such as polyethylene glycol, polyethylene ester, gelatin, polysaccharides, cellulosics in non-aqueous solvents, guar gum and the like, where polyethylene glycol is the preferred binder, (col. 5, lines 32-44; 58-60).

It would have been obvious to a person of ordinary skill at the time the invention was made to have modified the teachings of Dugger of buccal non polar spray or capsule by adding a solvent or binder such as polyethylene glycol, as taught by Robinson et al, because of the expectancy of producing a pharmaceutical composition containing a preferred solvent and an improved solubility.

#### ***Allowable Subject Matter***

Claims 10-11 and 20-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

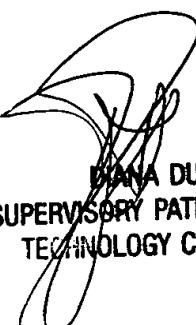
***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Daniel (5,457,100).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mina Haghigatian whose telephone number is 703-308-6330. The examiner can normally be reached on MON-FRI from 9:30AM to 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703-308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0198.



DIANA DUDASH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

Mina haghigatian  
Patent Examiner  
Art Unit 1619

June 4, 2001